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TOXICOLOGY DEPARTMENT

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US Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP ID No.: 8ECAP - 0004

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc. (RPI, CN 5266, Princeton, NJ 08543-5266) and its subsidiary Rhône-Poulenc Ag Company (RPAC), the attached study report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for a TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA.

The enclosed study report provides information on MCTR-131-78. We have diligently searched our files and have not been able to determine the chemical identity of this compound. This chemical was synthesized 10 to 20 years ago for pesticide research and development purposes.

No claims of confidentiality are made for this submission. The title of the enclosed report is "Report on Rabbit Eye Irritation". The following is a summary of the adverse effects observed in this study.

This report is being submitted under Section 8(e) because of systemic toxicity observed in the eye irritation study. Four of six rabbits died within 24 hours of instillation of 0.1 ml of test material into the eye. These deaths were considered to be treatment-related. In addition, severe and persistent eye irritation was observed in the surviving animals.

No previous TSCA Section 8(e) notices have been submitted on this chemical, but several will be submitted under the CAP.

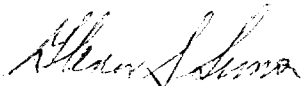
Three copies of the report and this cover letter are provided, i.e. one original and two copies.

2/8/95

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Further questions regarding this submission may be directed to the undersigned at 919-549-2222.

Sincerely,

A handwritten signature in cursive script, appearing to read "Glenn S. Simon".

Glenn S. Simon, PhD, DABT
Director of Toxicology

Cannon Laboratories, Inc.

P. O. Box 3627, Reading, Pa. 19605 (215) 375-4536

REPORT ON RABBIT EYE IRRITATION

SUBMITTED TO: MOBIL OIL COMPANY
ENVIRONMENTAL AFFAIRS & TOXICOLOGY
P.O. BOX 1026
PRINCETON, NEW JERSEY 08540

REFERENCE: Notebook Mob-001 87-89
LABORATORY NUMBER: 8E-2478

MOBIL SAMPLE: MCTR-131-78 (a clear volatile liquid)

DATE RECEIVED: 8/2/78

DATE COMPLETED: 8/14/78

PROCEDURE: Six prescreened New Zealand albino rabbits were used in this study. One-tenth of a milliliter of test material was instilled into the conjunctival sac of one eye of each rabbit on day 0 with the contralateral eye serving as a control. In the six rabbits, the treated eyes remained unwashed. The ocular reactions were graded at 1, 24, 48, 72 hours, 4 and 7 days after instillation in accordance with section 1500.42 of the Federal Hazardous Substance Act.

The results are summarized below and the scale for grading ocular reactions appears in Table I, while the individual eye scores and observations are presented in Table II.

NO WASH - 6 RABBITS

Cornea

NUMBER OF RABBITS WITH SIGNS					
HOUR				DAY	
1	24	48	72	4	7

(A) Opacity -

No ulceration or opacity	0	0	0	0	0	0
Scattered or diffuse areas of opacity	0	0	0	0	1	1
Easily discernible translucent areas of opacity	2	0	1	1	0	0
Nacreous areas of opacity, no details of iris visible	3	2	1	1	1	1
Complete corneal opacity, iris not discernible	0	0	0	0	0	0

(B) Area of Cornea Involved -

Normal	0	0	0	0	0	0
One quarter, but less than half	0	0	0	0	0	0
Greater than quarter, but less than half	0	0	0	0	0	0
Greater than half, but less than three quarters	2	2	2	2	2	2
Greater than three quarters, up to whole area	3	0	0	0	0	0

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NO WASH - 6 RABBITS

Iris

- (A) Normal
- (B) Markedly deepened folds, congestion, swelling, moderate circumcorneal injection, iris still reacting to light

NUMBER OF RABBITS WITH SIGNS					
HOUR				DAY	
1	24	48	72	4	7

0	0	0	0	0	0
4	2	2	2	2	2

Conjunctivae

- (A) Redness -
- Vessels normal
- Some vessels definitely injected
- Diffuse crimson red, individual vessels not easily discernible
- Diffuse beefy red
- (B) Chemosis -
- No swelling
- Any swelling above normal
- Obvious swelling, partial eversion of lids
- Swelling with lids about half closed
- Swelling with lids more than half closed
- (C) Discharge -
- No discharge
- Any amount different from normal
- Discharge with moistening of the lids and hairs adjacent to lids
- Discharge with moistening of the lids and hairs and considerable area around the eye

0	0	0	0	0	0
0	0	0	0	0	0
5	0	0	0	0	0
0	2	2	2	2	2
0	0	0	0	0	0
0	0	0	0	0	0
3	0	0	0	1	1
2	2	2	2	1	1
0	0	0	0	0	0
1	0	0	0	0	0
3	0	0	0	0	0
1	0	0	1	1	1
0	2	2	1	1	1

RESULTS: When tested in accordance with the Federal Hazardous Substance Labeling Act, 'MCTR-131-78' is considered to be an eye irritant. Death occurred in one rabbit prior to the one-hour scoring and in three additional rabbits prior to the 24-hour scoring. The death of these animals was compound-related as verified by the staff pathologist.

Cannon Laboratories, Inc.

Mobil - 'MCTR-131-78'

8E-2478

Performed By: Luann Seaman
Luann Seaman
Technician

Supervised By: Patricia E. Doyle
Patricia E. Doyle
Biologist, Study Director

Approved By: Herbert L. Ratcliffe
Herbert L. Ratcliffe, Sc.D., H.D.V.M.
Staff Pathologist

Reviewed By: Barke
Quality Assurance Unit

Cannon Laboratories, Inc.

TABLE I: GRADES FOR OCULAR REACTIONS

	<u>Cornea</u>	<u>Grade</u>
(A) Opacity		
No ulceration or opacity		0
Scattered or diffuse areas of opacity; details of iris clearly visible		1*
Easily discernible translucent areas of opacity; details of iris slightly obscured		2*
Nacreous areas of opacity; no details of iris visible; size of pupil barely discernible		3*
Complete corneal opacity; iris not discernible		4*
	<u>Iris</u>	
(A) Values		
Normal		0
Markedly deepened folds; congestion; swelling; moderate circumcorneal injection; iris still reacting to light		1*
No reaction to light; hemorrhage; gross destruction		2*
	<u>Conjunctivae</u>	
(A) Redness		
Vessels normal		0
Some vessels definitely injected		1
Diffuse crimson red; individual vessels not easily discernible		2*
Diffuse beefy red		3*
(B) Chemosis		
No swelling		0
Any swelling above normal		1
Obvious swelling; partial eversion of lids		2*
Swelling with lids about half closed		3*
Swelling with lids more than half closed		4*

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TABLE 1: GRADES FOR OCULAR REACTIONS (CONT'D.)

	<u>Conjunctivae</u>	<u>Grade</u>
(C) Discharge		
No discharge		0
Any amount different from normal (does not include small amounts observed in inner canthus of normal animals)		1
Discharge with moistening of the lids and hairs just adjacent to lids		2
Discharge with moistening of the lids and hairs and considerable area around the eye		3

*Grades considered positive for irritation.

"An animal should be considered as exhibiting a positive reaction if the test substance produced, at any of the readings, ulceration of the cornea (other than a fine stippling); opacity of the cornea (other than a slight dulling of the normal luster); inflammation of the iris (other than a slight deepening of the folds; of rugae, or a slight circumcorneal injection of the blood vessels); or if such substances produce in the conjunctivae (excluding the cornea and iris) an obvious swelling with partial eversion of the lids or a diffuse crimson red with individual vessels not easily discernible. 1"

1 Federal Register, Vol. 38, No. 187 - September 27, 1973, p 27019

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TABLE II: EYE IRRITATION IN RABBITS

ANIMAL NUMBER	CORNEA A X B X 5		IRIS A X 5	CONJUNCTIVAE (A + B + C) X 2			TOTAL SCORE PER ANIMAL
One Hour							
No Wash	A	B	A	A	B	C	
3848	2	4	1	2	2	1	55
3743	3	3	1	2	2	0	58
3858	3	3	1	2	3	2	64
3857	2	4	1	2	3	1	57
3992	3	4	*	2	2	1	70
3849	Death		-	-	-	-	-
24 Hours							
No Wash							
3848	Death		-	-	-	-	-
3743	Death		-	-	-	-	-
3858	3	3	1	3	3	3	68
3857	3	3	1	3	3	3	68
3992	Death		-	-	-	-	-
3849	-	-	-	-	-	-	-

*Iris could not be seen due to corneal opacity

- = animal dead

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TABLE II: EYE IRRITATION IN RABBITS

ANIMAL NUMBER	CORNEA A X B X 5		IRIS A X 5	CONJUNCTIVAE (A + B + C) X 2			TOTAL SCORE PER ANIMAL
48 Hours							
No Wash	A	B	A	A	B	C	
3848	-	-	-	-	-	-	-
3743	-	-	-	-	-	-	-
3858	3	3	1	3	3	3	68
3857	2	3	1	3	3	3	53
3992	-	-	-	-	-	-	-
3849	-	-	-	-	-	-	-
72 Hours							
No Wash							
3848	-	-	-	-	-	-	-
3743	-	-	-	-	-	-	-
3858	3	3	1	3	3	3	68
3857	2	3	1	3	3	2	51
3992	-	-	-	-	-	-	-
3849	-	-	-	-	-	-	-

- = animal dead

Cannon Laboratories, Inc.

TABLE II: EYE IRRITATION IN RABBITS

ANIMAL NUMBER	CORNEA A X B X 5		IRIS A X 5	CONJUNCTIVAE (A + B + C) X 2			TOTAL SCORE PER ANIMAL
4 Days							
No Wash	A	B	A	A	B	C	
3848	-	-	-	-	-	-	-
3743	-	-	-	-	-	-	-
3858	3	3	1	3	3	3	68
3857	1	3	1	3	2	2	34
3992	-	-	-	-	-	-	-
3849	-	-	-	-	-	-	-
7 Days							
No Wash							
3848	-	-	-	-	-	-	-
3743	-	-	-	-	-	-	-
3858	3	3	1	3	3	3	68
3857	1	3	1	3	2	2	34
3992	-	-	-	-	-	-	-
3849	-	-	-	-	-	-	-

- = animal dead



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Glenn S. Simon, Ph.D., DABT
Director of Toxicology
Rhône-Poulenc
P.O. Box 12014
2 T.V. Alexander Drive
Research Triangle Park, North Carolina 27709

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAR 20 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12026A



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CAPSubmission number: 12026A

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Notes:

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Tox Concern

ID
12026A

ATOX

H

Prod
U

COMMENT

TOXICITY BY THE OCULAR ROUTE IN RABBITS IS OF HIGH CONCERN. SEVERE AND PERSISTENT IRRITATION WAS OBSERVED FOLLOWING APPLICATION OF 0.1 ML INTO THE CONJUNCTIVAL SAC OF SIX NEW ZEALAND WHITE RABBITS. DEATH OCCURRED IN 4/6 RABBITS. CORNEAL OPACITY, IRITIS, AND CONJUNCTIVAL IRRITATION WERE NOTED IN THE TWO SURVIVING RABBITS.

12026A

H

Severe eye irritation is of high concern.

Primary eye irritation in rabbits is of high concern. Severe and persistent irritation was observed following application of 0.1 mL into the conjunctival sac of six New Zealand white rabbits. Death occurred in 4/6 rabbits. Corneal opacity, iritis, and conjunctival irritation were noted in the two surviving rabbits.